

# MATERIAL SAFETY DATA SHEET

Boehringer Ingelheim  
Pharmaceuticals, Inc.  
900 Ridgebury Rd  
Ridgefield, CT 06877

Product name: Ipratropium Bromide

DATE ISSUED: 11/10/05

**EMERGENCY TELEPHONE NUMBER**  
**CHEMTREC - 24 hours**  
**1-800-424-9300**

## 1. SUBSTANCE IDENTIFICATION

CHEMICAL NAME: (endo,syn)-(+)-8-methyl-8-(1-methylethyl)-8-azabicyclo(3.2.1)-3-yl-(2-hydroxy-2-phenyl)acetate Methylbromide

CAS TYPE: 1

MOLECULAR FORMULA: C<sub>20</sub>H<sub>30</sub>BrNO<sub>3</sub>

TRADEMARK:

MOLECULAR WEIGHT: 412.47

CHEMICAL FAMILY: quaternary ammonium  
anticholinergic

CAS NUMBER: 22254-24-6

PRODUCT USE: bronchodilator

SYNONYMS: 8-isopropyloratropine methobromide

## 2. HAZARD IDENTIFICATION

### EMERGENCY OVERVIEW

White odorless crystalline powder. Caution: harmful by inhalation and if swallowed. Do not allow product to reach ground water, water bodies or sewage system. Up to 180 °C no observation of exothermic decomposition (DTA).

The product is used as a pharmaceutical active substance. All precautions for drugs and pharmaceuticals should thoroughly be observed.

ROUTES OF ENTRY: Inhalation, ingestion, eye and skin contact.

TARGET ORGANS: Respiratory system

ACUTE EXPOSURE: Inhalation may cause dryness of mucous membranes, tachycardia, thirst, excitement, disorientation, hallucinations, delirium and fever. Skin contact may cause rash and irritation.

CHRONIC EXPOSURE: Possible hypersensitization

MEDICAL CONDITIONS POTENTIALLY AGGRAVATED BY EXPOSURE: Previous hypersensitivity to atropine and its derivatives, narrow angle glaucoma, prostatic hypertopy, bladder-neck obstruction.

CARCINOGENICITY: Not listed/listed as carcinogen or potential carcinogen by NTP, IARC Monographs or OSHA.

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### 3. COMPONENTS PER UNIT DOSE

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MATERIAL	WEIGHT %	EXPOSURE LIMITS
Active Ingredient:	100%	15 ug/m3**

\*\*BIEL is the BI Exposure Control Level. When lower governmentally imposed occupational exposure limits exist, such limits should take precedence.

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### 4. EMERGENCY FIRST AID PROCEDURES

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**INHALATION:** Remove from area to fresh air. Seek medical attention if respiratory irritation develops or if breathing becomes difficult.

**INGESTION:** Rinse out mouth then give 3-4 glasses of water, but **DO NOT** induce vomiting. If vomiting occurs, give fluids again. Get medical attention to determine whether vomiting or evacuation of stomach is necessary. Do not give anything by mouth to an unconscious or convulsing person.

**SKIN CONTACT:** Remove contaminated clothing. Wash affected areas with plenty of water, and soap if available, for several minutes. Seek medical attention if irritation or rash develops and persists.

**INJECTION:** In case of accidental injection, wash and thoroughly disinfect, get medical attention.

**EYE CONTACT:** Flush eyes with large amounts of running water for 15 minutes. Get immediate medical attention.

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### 5. FIRE AND EXPLOSION HAZARD DATA

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Flash Point	Flammable Limits	
	Upper	Lower
ND	ND	ND

FIRE EXTINGUISHING MEDIA: Carbon dioxide extinguishing powder or jet. Fight large fires with water.

SPECIAL FIRE FIGHTING PROCEDURES: As with all fires, evacuate personnel to safe area. Firefighters should use self-contained breathing equipment and protective clothing. Use water spray to keep fire-exposed containers cool and protect against all exposures.

UNUSUAL FIRE AND EXPLOSION HAZARDS: As with all organic powders, this material presents a dust explosion hazard. It can burn in a fire, producing acrid flammable fumes including acid gases, oxides of carbon and nitrogen and hydrogen bromide.

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### 6. SPILL AND ACCIDENTAL RELEASE MEASURES

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STEPS TO BE TAKEN IN THE EVENT OF A SPILL: Wear approved respirator and chemically compatible gloves if containers have been compromised. Vacuum or sweep up spillage. Avoid creating dust. Place spillage in appropriate container for waste disposal. Wash contaminated clothing before

reuse. Ventilate area, wash down spill site and control wash water. Do not allow product to reach sewage system or waterway.

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## 7. PRECAUTIONS FOR SAFE HANDLING AND USE

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**HANDLING AND STORAGE PRECAUTIONS:** Avoid contact with eyes, skin or clothing. Avoid breathing dust. Avoid generating dust. Store in tight, light-resistant containers away from foodstuffs.

**OTHER PRECAUTIONS:** Wash thoroughly after handling material. Wear fresh clothing daily. Wash contaminated clothing before reuse.

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## 8. CONTROL MEASURES

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**ENGINEERING CONTROLS:** Minimize dust generation. Use closed equipment where possible. Use spot ventilation to remove dust from the work area. If operations generate dusts, use explosion-proof ventilation equipment to control airborne levels. Use appropriate respiratory protection based on an industrial hygiene survey.

**RESPIRATORY PROTECTION:** A qualified person should determine the need for respiratory protection. NIOSH/MSHA approved respirators for protection should be used if respirators are found to be necessary.

**PERSONAL PROTECTIVE EQUIPMENT**

Eye Protection: Safety glasses with side shields or goggles	Hand Protection: PVAC gloves
Protective Clothing: Laboratory coats or protective work clothing	Other: Eye wash & safety shower

**WORK/HYGIENIC PRACTICES:** Do not permit eating, drinking or smoking near this material. Wash thoroughly after handling material, before eating and at the end of work.

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## 9. PHYSICAL/CHEMICAL CHARACTERISTICS

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**APPEARANCE AND ODOR:** White odorless crystalline powder

Boiling Point: N/D

Vapor Pressure (mm Hg): N/A

Vapor Density: N/A

Water Solubility: Soluble

Specific Gravity: N/D

Melting Point: 231 oC

Evaporation Rate: N/A

Volatiles, %: N/A

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## 10. REACTIVITY DATA

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**STABILITY:** Stable

**CONDITIONS TO AVOID:** None known

**INCOMPATIBLE MATERIALS:** Oxidizing materials.

**HAZARDOUS DECOMPOSITION OR BY-PRODUCTS:** When heated to decomposition or under fire conditions, material emits toxic fumes including acid gases and oxides of nitrogen and carbon and hydrogen bromide.

**HAZARDOUS POLYMERIZATION:** Will not occur.

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## 11. TOXICOLOGICAL INFORMATION

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## ACUTE TOXICITY

TDLO/TCLO - LOWEST PUBLISHED TOXIC DOSE/CONC

*Man* TCLO - ROUTE: Inhalation; DOSE: 1 ug/kg TOXIC EFFECTS: *Gastrointestinal* - Other changes

LDLO/LCLO - LOWEST PUBLISHED LETHAL DOSE/CONC

*Dog* LDLo - ROUTE: Intravenous; DOSE: 20 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

LD50/LC50 - LETHAL DOSE/CONC 50% KILL

*Rat* LD50 - ROUTE: Intraperitoneal; DOSE: 113 mg/kg TOXIC EFFECTS: *Behavioral* – Ataxia *Behavioral* – Tetany *Lung, Thorax, or Respiration* - Dyspnea

LD50 - ROUTE: Intravenous; DOSE: 15700 ug/kg

LD50 - ROUTE: Oral; DOSE: 1663 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

LD50 - ROUTE: Subcutaneous; DOSE: 635 mg/kg TOXIC EFFECTS: *Behavioral* – Ataxia *Behavioral* – Tetany *Lung, Thorax, or Respiration* - Dyspnea

*Mouse* LD50 - ROUTE: Intraperitoneal; DOSE: 72 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Coma *Lung, Thorax, or Respiration* - Respiratory depression

LD50 - ROUTE: Intravenous; DOSE: 12290 ug/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

LD50 - ROUTE: Oral; DOSE: 1001 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

LD50 - ROUTE: Subcutaneous; DOSE: 300 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

*Rabbit* LD50 - ROUTE: Oral; DOSE: 1557 mg/kg TOXIC EFFECTS: *Behavioral* – Tremor *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Respiratory depression

*Dog* LD50 - ROUTE: Oral; DOSE: 1300 mg/kg TOXIC EFFECTS: *Behavioral* - Convulsions or effect on seizure threshold *Behavioral* – Ataxia *Lung, Thorax, or Respiration* - Dyspnea

## IRRITATION

EYE - STANDARD DRAIZE TEST

*Rabbit* ROUTE: Eyes; DOSE: 100 mg/24H; REACTION: Moderate

## REPRODUCTIVE EFFECTS

*Rat* TDLo - ROUTE: Oral; DOSE: 30 gm/kg; DURATION: male 60D prior to mating TOXIC EFFECTS: *Paternal Effects* - Testes, epididymis, sperm duct *Paternal Effects* - Prostate, seminal vesicle, Cowper's gland, accessory glands

TDLo - ROUTE: Oral; DOSE: 55 mg/kg; DURATION: female 7-17D of pregnancy TOXIC EFFECTS: *Effects on Fertility* - Pre-implantation mortality (e.g., reduction in number of implants per female; total number of implants per corpora lutea) *Specific Developmental Abnormalities* - Musculoskeletal system

TDLo - ROUTE: Oral; DOSE: 550 mg/kg; DURATION: female 7-17D of pregnancy TOXIC EFFECTS: *Maternal Effects* – Parturition *Effects on Newborn* - Viability index (e.g., # alive at day 4 per # born alive)

*Rabbit* TDLo - ROUTE: Oral; DOSE: 1120 mg/kg; DURATION: male 28D prior to mating TOXIC EFFECTS: *Paternal Effects* - Prostate, seminal vesicle, Cowper's gland, accessory glands

TDLo - ROUTE: Oral; DOSE: 65 mg/kg; DURATION: female 6-18D of pregnancy TOXIC EFFECTS: *Effects on Fertility* - Litter size (e.g., # fetuses per litter, measured before birth)

#### **OTHER MULTIPLE DOSE TOXICITY DATA**

*Rat* TDLo - ROUTE: Oral; DOSE: 35 gm/kg/5W intermittent TOXIC EFFECTS: *Brain and Coverings* - Changes in brain weight *Cardiac* - Changes in heart weight *Biochemical* - Phosphatases

TDLo - ROUTE: Oral; DOSE: 91 gm/kg/26W continuous TOXIC EFFECTS: *Kidney, Ureter, and Bladder* - Other changes in urine composition *Kidney, Ureter, and Bladder* - Changes in bladder weight *Endocrine* - Changes in adrenal weight

*Rabbit* TDLo - ROUTE: Oral; DOSE: 11200 mg/kg/4W continuous TOXIC EFFECTS: *Endocrine* - Other changes *Blood* - Changes in serum composition (e.g., TP, bilirubin, cholesterol) *Nutritional and Gross Metabolic* - Weight loss or decreased weight gain

TERATOGENICITY: negative reproductive studies in mice, rats, and rabbits, and negative teratogenicity studies in rats and rabbits at doses several hundred to several thousand times the recommended human dose. Published teratology studies have also been negative in rats and rabbits

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### **12. ECOLOGICAL INFORMATION**

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Water Danger Class 3 (Germany). Extremely hazardous for water. Do not allow product to reach ground water, water bodies or sewage system.

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### **13. DISPOSAL CONSIDERATIONS**

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WASTE DISPOSAL CONSIDERATIONS: WASTE DISPOSAL CONSIDERATIONS: Dispose of in accordance with local, state and federal regulations. Recommended method is incineration.

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### **14. TRANSPORT INFORMATION**

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DOT Proper Shipping Name:	N/A	Packing Group:	N/A
Hazard Class:	N/A	Identification Number:	N/A

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### **15. REGULATORY INFORMATION**

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This material is **not** listed on the US TSCA Inventory. Therefore, it can only be used for TSCA exempt purposes such as R&D or drug use.

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### **16. OTHER INFORMATION**

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#### ABBREVIATIONS:

N/E: Not Established  
N/A: Not Applicable  
N/D: Not Determined

Prepared by: Environmental Affairs & Safety  
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REVISION INFORMATION: Updated and reformatted Sections 2 & 3.

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1. Physicians Desk Reference, 1974-2000 Edition
2. Drugdex – Drug Evaluations
3. The ReproTox System, 1991-2000. Reproductive Toxicology Center.